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THIS ISSUE

Guideline for the use of Neurontin® in the Management of Neuropathic Pain

TO:

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Purpose and Development of the Guideline

The purpose of this guideline is to provide assistance to treating physicians in the use of Neurontin® in the management of neuropathic pain. Neuropathic pain may be defined as pain initiated or caused by a primary lesion or dysfunction in the nervous system, and is characterized by spontaneous pain described as lancinating, paroxysmal, burning, constant, cramping; and evoked pain of dysesthesia, allodynia, hyperalgia, or hyperpathia.

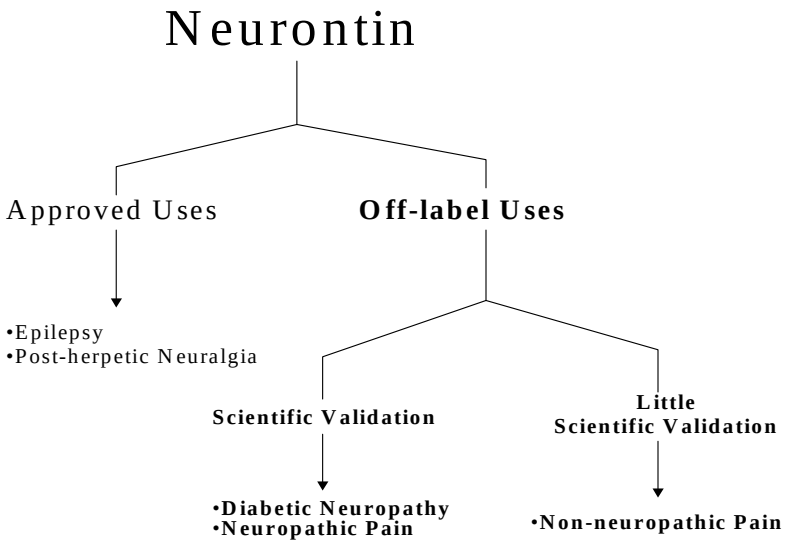
This guideline was developed by the Washington Department of Labor and Industries in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance Advisory Section of the Interspecialty Council. The guideline is based on a literature review of the current scientific information regarding the use of Neurontin® in the treatment of neuropathic pain, and on expert opinion from actively practicing physicians who regularly treat chronic, neuropathic pain.

This Provider Bulletin becomes effective 02/01/2003.

Literature Review on Neurontin®

The Food and Drug Administration (FDA) approved Neurontin® (gabapentin) in 1994 as an adjunctive treatment for partial seizures. Recently, the FDA also approved Neurontin® for treatment of post-herpetic neuralgia. Multiple randomized placebo-controlled studies have been published which demonstrated the efficacy of gabapentin in the management of neuropathic pain associated with diabetic peripheral neuropathy and neuropathic pain[1] [2] [3] following spinal cord injury. [4] Published research does not demonstrate that gabapentin significantly reduces the level of acute pain, myofascial pain, low back pain, or other sources of somatic pain commonly seen in workers' compensation. [5]

The diagram below summarizes Neurontin® use.



1 Backonja M, Beydoun A, Edwards K et al. Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus: a randomized controlled trial. JAMA;1998;280:1831-36.
2 Morello C, Leckband S, Stoner C et al. Randomized double-blind study comparing the efficacy of gabapentin with amitriptyline on diabetic peripheral neuropathy pain. Archives of internal Medicine;1999;159:1931-37.
3 Gorson K, Schott C, Herman R et al. Gabapentin in the treatment of painful diabetic neuropathy: a placebo controlled, double blind, crossover trial. Journal of Neurology, Neurosurgery & Psychiatry;1999;66:251-52.
4 Tai Q, Kirshblum S, Chen B et al. Gabapentin in the treatment of neuropathic pain after spinal cord injury: a prospective, randomized, double-blind, crossover trial. Journal of Spinal Cord Medicine;2002;25:100-05.
5 Rosenberg J, Harrell C, Ristic H et al. The effect of gabapentin on neuropathic pain. The Clinical Journal of Pain;1997;13:251-55.

Treatment Guideline for the use of Neurontin® for Neuropathic Pain

Since gabapentin is currently only available under the trade name Neurontin®, the trade name will be used in this guideline. Neurontin® has been approved for use in the treatment of post-herpetic neuralgia and there is scientific research that indicates it may be effective in the treatment of other conditions that result in neuropathic pain. There is no scientific evidence that Neurontin® is effective in treating acute pain, somatic pain from sprains or strains, or myofascial pain.

In this guideline, chronic pain has been classified into three categories with recommendations for use of Neurontin® for each category:

Category 1

Neurontin® is most likely to be effective when it is prescribed for the following neuropathic pain conditions:

- ✓ Peripheral nerve injury
- ✓ Peripheral polyneuropathy
- ✓ Cauda equina syndrome
- ✓ Spinal cord injury
- ✓ Complex Regional Pain Syndrome Type II (CRPS Type II)
- ✓ HIV and cancer related neuropathies
- ✓ Radiculopathy, chronic, not acute
- ✓ Other conditions with objective finding of nerve injury and a clearly documented history of neuropathic symptoms

Category 2

Neurontin® is less likely to be effective when it is prescribed for questionable neuropathic pain conditions with no objective findings of nerve injury, such as CRPS Type I. Accordingly, prescriptions for Neurontin® for questionable neuropathic pain conditions with no objective findings of nerve injury should be written only after prior consultation and recommendation from a physician specializing in pain therapies, rehabilitation and physical medicine, or neurology.

Category 3

There is no credible scientific evidence that Neurontin® is effective in relieving pain associated with the following non-neuropathic pain conditions:

- ✓ Acute musculoskeletal pain
- ✓ Primary somatic pain from chronic musculoskeletal strain/sprain
- ✓ Low back pain without radiculopathy
- ✓ Tendinitis
- ✓ Repetitive strain without evidence of entrapment neuropathy

Payment for Neurontin® may be denied by the claim manager when prescribed for conditions listed in Category 3; or for conditions listed in Category 2 without a prior consultation and recommendation from a physician specializing in pain therapies, rehabilitation and physical medicine, or neurology. Please contact the unit Occupational Nurse Consultant if there are any questions.

Recommended Dosage (Neurontin® Package Insert. May 2002)[6]

Individual drug tolerance and pain-relief dosage may vary considerably, however, Neurontin® effectiveness in reducing neuropathic pain should be seen by 4 to 6 weeks. The following is a recommended dosing plan for Neurontin® in the management of neuropathic pain.

Neurontin® therapy may be initiated as a 100 to 300 mg dose at bedtime and increased to 600 to 900 mg/day over 3 days (given in three divided doses). If this is tolerated, the dose may be titrated up every 2 to 3 days as tolerated until a daily dose of 1800 mg/day (given in three divided doses) is reached. If significant pain relief is achieved at a lower dose and no increased improvement is noted with further dose increases, the lower dose should be maintained.

If no improvement is seen with Neurontin® at 1800 mg/day, the dose may be increased up to 2400 mg/day. If no improvement is seen at 2400 mg/day, consider tapering Neurontin® to see if pain level increases. If pain level remains the same, discontinue Neurontin®. As no additional benefit is seen with doses greater than 1800 mg/day and the absorption of Neurontin® follows saturation biokinetics (an increasing dose of Neurontin® results in a decreasing percentage of Neurontin® absorption), further increases in doses are not recommended.

The most common side effects associated with the use of Neurontin® in adults are dizziness, somnolence, and peripheral edema. Accordingly, patients should be advised not to drive a car or operate other complex machinery until they have gauged whether or not Neurontin® affects their mental and/or motor performance.

In addition, patients who require concomitant treatment with morphine may experience increases in gabapentin concentrations and should be observed for signs of CNS depression and the dose of Neurontin® or morphine should be reduced appropriately. Please refer to Neurontin® Package Insert for complete prescribing instructions.

[6] Neurontin® Package Insert. May 2002

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